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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,052	09/28/2000	Michael K. Skinner	252/124	9790

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EXAMINER

WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/676,052	SKINNER ET AL.
	Examiner	Art Unit
	Ethan Whisenant, Ph.D.	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 December 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 17-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 10 DEC 02 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendment filed 10 DEC 02 has now been entered (Amdt. B). Claim(s) 1-21 are now pending with **Claim(s) 17-21** under examination and Claim(s) 1-16 withdrawn as the result of a restriction requirement.

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) The invention was described in –
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

5. **Claim(s) 17** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pinkel et al. [Nature Genetics (1998)].

Claim 17 is drawn to a physical platform comprising an array of nucleic acid polymers immobilized at predetermined positions on a solid support wherein the array comprises at least two different nucleic acid polymers each of which are specific for a different gene associated with lipid metabolism, synthesis or action. In addition, the array is to be hybridized with genomic DNA derived from a patient tissue sample which genomic DNA is to be detectable by a label at the predetermined positions. Finally the detection of the label at the predetermined positions is to indicate a difference in copy number of at least two different genes associated lipid metabolism, synthesis or action.

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Pinkel et al teach (see, for example, Table 1) an array of polymers comprising all of the limitations recited in Claim 17 except these authors do not explicitly teach that the at least two different nucleic acid polymers arrayed on their platform should be genes associated with lipid metabolism, synthesis or action. However, it can be argued that any/all gene(s) are “associated” with lipid metabolism, synthesis or action to some degree in that they are required for the proper functioning of cells/organisms and thereby allow gene(s) **directly** involved with lipid metabolism, synthesis or action to function.

Regardless, it is examiners position, that absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add any **known** gene or genomic locus (i.e. cDNA or EST) to an array of known genes/ESTs in order to analyze the copy number of genomic sequences in different cancer(s)/cell lines as suggested by Pinkel et al. See, for example, the last four sentences of the abstract in Column 1 on page 207 and Column 1 on page 210. As all of the genes recited in Claim 18-19, were known, it would appear to the examiner there was more than ample teachings in the prior to motivate the ordinary artisan to add any **known** gene (i.e. cDNA or EST) to arrays of known genes/ESTs in order to analyze the copy number of genomic sequences in different cancer(s)/cell lines.

CLAIM REJECTIONS UNDER 35 USC § 103

6. **Claim(s) 18-20** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. [Nature Genetics (1998)] as applied above and further in view of in view of Gao et al. (1994) and/or Fukushima et al. (FEB 1993 - Abstract only) and/or Goetzl et al. (SEP 1999 - Abstract only) and/or Haapamaki et al. (MAR 1999 - Abstract only) and/or Gibbs et al. (SEP 1999 - Abstract only) and/or Lockhart et al. (1996).

Claim 18 is drawn to an embodiment of Claim 17 wherein the at least two different nucleic acid polymers which are specific for two different gene(s) associated with lipid metabolism, synthesis or action are selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2.

Claim 19 is drawn to an embodiment of Claim 17 wherein the at least two different nucleic acid polymers which are specific for two different gene(s) associated with lipid metabolism, synthesis or action are selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2.

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Pinkel et al as argued above teach an array of nucleic acid polymers comprising all of the limitations recited in Claim(s) 18-19 except these authors do not explicitly teach that the at least two different nucleic acid polymers which are specific for two different gene associated with lipid metabolism, synthesis or action are selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2. However, as evidenced by Gao et al. and/or Fukushima et al. and/or Goetzl et al. and/or Haapamaki et al. and/or Gibbs et al. and/or Lockhart et al. all of these genes were known. Therefore, in view of the cumulative teachings in the prior art, and absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the array(s) taught by Pinkel et al. wherein the array comprises nucleic acid polymers which are specific for Phospholipase A2, Phospholipase D1, Edg-1, Edg-2, Edg-3, Edg-4, and Edg-5. The ordinary artisan would have been motivated to modify the array of Pinkel et al. in order to analyze the copy number of these genomic sequences in the most expeditious way possible; which at the time of the invention was the array methodology taught by Pinkel et al.

To reiterate, it is examiners position, that absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add any **known** gene or genomic locus (i.e. cDNA or EST) to an array of known genes/ESTs in order to analyze the copy number of genomic sequences in different cancer(s)/cell lines as suggested by Pinkel et al. See, for example, the last four sentences of the abstract in Column 1 on page 207 and Column 1 on page 210. As all of the genes recited in Claim 18-19, were known, it would appear to the examiner there was more than ample teachings in the prior to motivate the ordinary artisan to add any **known** gene (i.e. cDNA or EST) to arrays of known genes/ESTs in order to analyze the copy number of genomic sequences in different cancer(s)/cell lines.

Claim 20 is drawn to an embodiment of Claim 17 wherein at least one of the isolated nucleic acid polymers comprise at least about 19 nucleotides.

Pinkel et al. is silent as regards the length of the gene sequences present on their arrays, however Pinkel et al. do teach that the arrays were fabricated with 40-80 μ g of P1 or BAC DNA. Therefore, the examiner, absent a showing to the contrary, believes that the length of the isolated nucleic acid polymers present on the arrays of Pinkel et al. were much longer than 19 nucleotides.

7. **Claim(s) 21** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. [Nature Genetics (1998)] as applied above and further in view of Bovenberg et al.[US 5,747,285 (1998)].

Claim 21 is drawn to an embodiment of Claim 17 wherein at least one of the nucleic acid polymers specific for the selected genes is a nucleic acid polymer comprising at least about 19 nucleotides and will hybridize to a non-coding sequence functionally linked to the coding region of one of the selected genes wherein said functionally linked non-coding sequence is unique to that gene.

Admittedly, Pinkel et al. do not explicitly teach the limitation wherein the selected genes is a nucleic acid polymer which hybridizes to a non-coding region functionally linked to one of the selected genes wherein the functionally linked sequence is unique to said gene. However, it was well known at the time of the invention that one could detect a target polynucleotide by hybridizing to a non-coding region of said target polynucleotide as long as said region was specific for said target. see for example Bovenberg et al. [US 5,747,285 (1998)]. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan in the art at the time of the invention that one could with a reasonable expectation of success hybridize to a non-coding sequence functionally linked to the coding region of one of the selected genes as long as the functionally linked sequence is unique to said gene. Motivation for modifying the array of Pinkel et al. comes from expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Absent an unexpected result, the substitution of one well known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

8. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are deemed to be moot in view of the new ground(s) of rejection.

CONCLUSION

9. **Claim(s) 17-21** is/are rejected and/or objected to for the reason(s) set forth above.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Art Unit is (703) 308-8724. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



Ethan Whisenant, Ph.D.
Primary Examiner